

#### **REMARKS/ARGUMENTS**

Claims 1-30 were pending in this application. Claims 4-6 and 13-22 have been withdrawn from consideration as being drawn to a non-elected species. Those claims are cancelled without prejudice in this amendment. Claims 1-3, 7-12 and 23-30 are drawn to the elected species and still under consideration.

Claims 1-3, 7-12 and 23-30 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the reasons stated in the Office Action. Applicants amend claims 1, 9, 23 and 25 by changing "a pump cycle" to "the pumping cycle" to provide proper antecedent basis and additional clarity. Similarly, Applicants amend claim 7 by changing "a stroke frequency" to "the stroke frequency" to provide proper antecedent basis and additional clarity. Applicants amend claims 9 and 10 by consistently referring to the beginning and end of the compression stroke, rather than the start and middle of the pumping cycle. These changes are believed to obviate the 112 rejection of claims 1-3, 7-12 and 23-30. The changes are supported by the original specification. No new matter has been added.

Claims 1-9, 11 and 25 were rejected under 35 U.S.C. 102(b) as being anticipated by Epstein et al. US 5,464,392. Claims 10 and 23-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein et al. '392 in view of Madsen et al. US 4,850,805. Claim 12 was rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein et al. '392 in view of Holst et al. US20030055375.

Claims 26-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein et al. '392 in view of Butterfield US20010007636. Claims 26-30 have been cancelled, making their rejection moot.

Claim 3 has been cancelled and its limitations have been incorporated into claim 1. Claim 8 has been cancelled and its limitations have been incorporated into claim 1. Claims 1, 23 and 25 have been amended to incorporate the limitations of claim 8, recite that the outlet valve is passive, and to clarify that the opening of the outlet valve is identified by the pressure state or pressure data from the pumping chamber. These changes are supported by the original specification. No new matter has been added. These changes are believed to distinguish the claimed invention over Epstein et al. and the other prior art of record for the reasons stated below.

Epstein et al. '392 discloses an infusion system that utilizes a unitary disposable cassette and multiple active valves to deliver multiple infusates at individually programmable

rates, volumes and sequences from plural fluid ports. The system is operative to adapt actual to desired flow rates in normal operation. Air bubbles are automatically detected and disposed of. Fluid pressures are monitored and system operation adjusted as a function of such pressures. (Abstract) However, a closer examination reveals some key differences between the system and method of Epstein et al. and the presently claimed invention.

First, Epstein et al. disclose a pump chamber 20/208 intermittently stroked by first plunger or pumping actuator 46/272 in FIGS. 1, 4 and 5 and a separate pressure chamber 22/212 located downstream of the pump chamber 20. A second plunger or pressure head 306 fastened to a pressure transducer 40 on linkage 310 monitors pressure at the pressure chamber 22/212 (C19, L30-39), not directly at the pump chamber 20. The pressure reading is subject to variations due to cassette installation and manufacturing tolerances, and may not accurately reflect the true pressure in the pump chamber 20 or its fluctuation over time.

Second, Epstein et al. disclose a system that relies on actively controlled valves. In particular, active inlet and outlet valves 18, 28 are required. These valves require actuator mechanisms 34 to operate them. (C5, L55-67) In fact, as best seen in FIGS. 5 and 6, a second motor and cam system is required to operate the valves. The active valves, valve operating mechanisms, and separate pressure chamber/sensor mechanism increases the size and complexity of both the cassette and the pump.

Thirdly, Epstein et al. disclose in the rolled out view of FIG. 8 an annular sleeve 338 mounted for rotation with the cam 314 and the stepper motor 316. The sleeve 338 has an open portion 342 and a closed portion 344. (C20, L21-31; C21, L23-34) An optical sensor detects can only detect the opened and closed portions at given points in the pumping sequence. This arrangement fails to provide any meaningful information about motor, cam or plunger position between the opened and closed portions. Thus, proper movement, operation, and relation of motor/plunger position to pump chamber pressure in the interim positions can only be assumed, and such data is not continuously gathered.

Finally, Epstein et al. disclose a method of processing data from the pressure sensor and position sensor that is different from the present invention. Epstein et al. require pre-pumping steps to determine the amount of air in the cassette and reach a certain pressure threshold before actual delivery will occur. This front end calculation and delivery method is an open loop approach that involves many delays that cannot be afforded, particularly in low flow situations. The present invention identifies when the outlet valve opens and calculates the actual volume delivered per stroke. This value is compared to a target nominal stroke

volume and is used to adjust the stroke frequency in a closed loop manner.

None of the other prior art references show or provide teaching to overcome the shortcomings of the Epstein et al. reference in a way that leads to the claimed invention. Thus, claims 1, 23, 25 and the claims depending therefrom are believed to be patentable.

New claim 31, which depends from claim 1 and at least derives its patentability therefrom, has been added to recite that the nominal pressurization volume comprises multiple nominal pressurization volumes averaged together. This can be for a particular pump or all pumps of a particular type, as described on page 16, lines 3-10 of the original specification.

A Petition for Extension of Time by three (3) months from October 26, 2007 to January 28, 2008 is submitted herewith along with the authorization for payment of the appropriate fees. No further extensions or fees are believed to be due in connection with this paper. However, the Commissioner is authorized to consider this a request for any necessary extension and charge our Deposit Account, 50-3118 for any additional fees (or credit any over payments) in association with this communication. A timely and favorable response on the merits of the claims as amended is respectfully requested.

Respectfully submitted,  
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